UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,897	04/06/2006	Augusto Amici	2503-1207	3387
466 YOUNG & TH	7590 03/04/201 OMPSON	EXAMINER		
209 Madison St		BURKHART, MICHAEL D		
Suite 500 Alexandria, VA	22314	ART UNIT	PAPER NUMBER	
			1633	
			NOTIFICATION DATE	DELIVERY MODE
			03/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summany		Арр	lication No.	on No. Applicant(s)			
		10/5	574,897	AMICI ET AL.			
Office Action Summary			miner	Art Unit			
		Mich	nael Burkhart	1633			
- Period fo	- The MAILING DATE of this communic r Reply	ation appears	on the cover sheet with the	correspondence a	ddress		
WHIC - Extens after S - If NO - Failure Any re	DRTENED STATUTORY PERIOD FO HEVER IS LONGER, FROM THE MA sions of time may be available under the provisions of BIX (6) MONTHS from the mailing date of this commu period for reply is specified above, the maximum statuse to reply within the set or extended period for reply within the se	ILING DATE (37 CFR 1.136(a). I nication. Itory period will apply ill, by statute, cause	OF THIS COMMUNICATIO In no event, however, may a reply be ting If y and will expire SIX (6) MONTHS from the application to become ABANDONI	N. mely filed the mailing date of this of ED (35 U.S.C. § 133).			
Status							
1) 又	Responsive to communication(s) filed	on 12/3/2009.					
•	This action is FINAL . 2b) ☐ This action is non-final.						
3)	, 						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositio	on of Claims						
 4) Claim(s) 14-26 is/are pending in the application. 4a) Of the above claim(s) 23-26 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 14-22 is/are rejected. 7) Claim(s) is/are objected to. 							
	Claim(s) are subject to restricti	on and/or elec	tion requirement.				
· · ·	on Papers						
•	The specification is objected to by the		or h)□ objected to by the	Evaminor			
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
					ER 1.121(d).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	nder 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
	of References Cited (PTO-892)	0.048)	4)				
3) 🔯 Inform	e of Draftsperson's Patent Drawing Review (PT nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date <u>4/6/2006</u> .	O- 94 8)	5) Notice of Informal 6) Other:				

DETAILED ACTION

Receipt and entry of the amendment dated 12/3/2009 is acknowledged. After entry of the amendment, claims 14-26 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

This application contains claims drawn to inventions nonelected with traverse in the reply filed on 5/13/2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

Claims 14-22 are objected to for reciting non-elected subject matter, i.e. any SEQ ID NO: other than SEQ ID NO: 2.

Claim Rejections - 35 USC § 102

Claims 14-17 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al, (Cancer Res., 1998, cited by applicants). This rejection is maintained for reasons made of record in the Office Action dated 9/3/2009, and for reasons set forth below.

Response to Arguments

Applicant's arguments filed 12/13/2009 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) the previous Office Action has interpreted the

Art Unit: 1633

claims to require the rat p185neu only, rather than comprising a rat and human chimeric sequence as taught in the specification and illustrated in an appendix; 2) the rat/human chimeric proteins are useful in inducing immunity against tumors; 3) Chen et al fail to teach a chimeric rat human protein according to the instant claims.

Regarding 1) and 3), the claims have been amended to remove the "coding for a fragment" language but remain subject to an open interpretation. The instant claims are worded with open language, i.e. the vectors comprise "a nucleotide sequence" of SEQ ID NO: 2. The selection of "a nucleotide sequence" from SEQ ID NO: 2 appears arbitrary, and may include the entire sequence, or a portion of the sequence. The first ¶ of the specification teaches that the vectors of the invention may encode "different fragments of human or rat p185neu." Hence, a DNA vector comprising the entire p185^{neu} rat gene is considered to be anticipatory of the claimed subject matter. Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the claims are limited to a rat/human chimeric protein comprising the entirety of SEQ ID NO: 2) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding 2), that an unclaimed protein encoded by the instant vectors has an intended use is not disputed at present. However, the bearing of this assertion on the instant rejection is unclear and not explained by applicants.

Application/Control Number: 10/574,897 Page 4

Art Unit: 1633

Claim Rejections - 35 USC § 103

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (Cancer Res., 1998, cited by applicants) in view of Krieg et al (U.S. patent 6,653,292).

This rejection is maintained for reasons made of record in the Office Action dated 9/3/2009, and for reasons set forth below.

Response to Arguments

Applicant's arguments filed 12/13/2009 have been fully considered but they are not persuasive. Applicants essentially assert that the claims 18 and 19 depend from claim 14, which is not anticipated by Chen et al, and Krieg et al do not make up the deficiencies of Chen et al.

Such is not convincing. Chen et al is not deemed to have any deficiencies for reasons set forth above. Hence, the rejection stands.

Double Patenting

Applicant is advised that should claim 21 be found allowable, claim 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). **This is a new warning necessitated by amendment of the claim dependency.**

Claim 21 recites a composition for parenteral administration, which by definition is an "injectable solution" as recited in claim 22. Thus, claim 22 does not appear to differ in scope from claim 21 in any meaningful way.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/ Primary Examiner, Art Unit 1633